



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Mental Health

Request for Information on the Availability of Biological Samples to Evaluate the
Technical Performance of Inflammatory Markers

SUMMARY: The National Institute of Mental Health (NIMH) seeks information about the availability of data and existing biological specimens (plasma and cerebrospinal fluid (CSF)) obtained from healthy controls and clinically well-characterized individuals with mental illnesses (bipolar disorder, major depressive disorder, post-traumatic stress disorder, schizophrenia). This information will be used to identify biobanks of existing samples that could potentially be sourced to assess the technical performance of a panel of inflammation-related proteins, and to identify gaps in the availability of samples for the mental illnesses listed above.

DATES: All responses must be submitted via email to biospecimens2@mail.nih.gov by August 4, 2016.

ADDRESSES: Please direct all inquiries to: biospecimens2@mail.nih.gov

FOR FURTHER INFORMATION CONTACT: Nancy L Desmond, PhD, Division of Neuroscience & Basic Behavioral Science, National Institute of Mental Health, National

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SUPPLEMENTARY INFORMATION: Sample collection, processing, and storage procedures have the potential to affect assay results for basic research, biomarker discovery, biomarker validation, and development of validated assays. Variability in these procedures may also decrease data rigor, thereby increasing the likelihood of irreproducible data, incorrect conclusions, and delays in advancing scientific knowledge.

Recent genetic studies have provided compelling evidence in support of the long-held hypothesis that alterations in immune function are associated with the pathophysiology of mental illnesses. Abnormal blood levels of cytokines have been reported in schizophrenia, bipolar disorder and major depressive illness. However, our understanding of the role of immune system markers in mental illnesses has not advanced due in part to between-study heterogeneity in immune assay methodology, diagnosis criteria, severity of disease, number and age of samples, and other potential confounds (e.g., medication, comorbidities) (Goldsmith, DR et al., Mol. Psychiatry, 23 February 2016; doi:10.1038/mp.2016.3).

The creation of an agreed upon, standard panel of pro- and anti-inflammatory markers, along with adoption of a standard approach for sample collection and handling, would be a valuable resource for evaluation of inflammatory processes in mental illnesses.

This request for information (RFI) seeks information from the community about the availability, quality, and degree of clinical characterization of plasma and CSF

samples that could potentially be used for assessing the technical performance of a panel of inflammatory markers and the utility of the panel for sub-typing individuals and tracking disease progression in individuals with mental illness.

The NIMH seeks information on the following:

1. Source and number of samples available for each disorder and for healthy controls. Include the number of plasma samples and the number of CSF samples available, and whether both plasma and CSF samples are available from the same individuals.
2. SOPs used for sample collection and storage
3. Available clinical data: diagnosis, age of onset and duration of illness, demographics, medications, co-morbidities
4. Consent for sharing of samples
5. Contact information for the individual responsible for the samples

Respondents are encouraged to include any other information that they deem relevant to the purpose of this RFI.

The NIH will use the information submitted in response to this RFI at its discretion and will not provide comments to any responder's submission. However, responses to the RFI may be reflected in future funding opportunity announcements. The information provided will be analyzed and may be aggregated in reports. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. No proprietary, classified, confidential, or sensitive information should be

included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).

Dated: June 16, 2016

Shelli Avenevoli, Ph.D.

Acting Deputy Director

National Institute of Mental Health

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